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Prescription Drug Design Liability Under the Proposed Restatement (Third) of Torts: A Reporter's Perspective

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PRESCRIPTION DRUG DESIGN LIABILITY UNDER THE PROPOSED RESTATEMENT (THIRD) OF TORTS: A REPORTER'S PERSPECTIVE*

*James A. Henderson, Jr.***

I. INTRODUCTION

At its annual meeting in May of 1995 the ALI approved much of Tentative Draft No. 2 of the Restatement (Third) of Torts: Products Liability,[1] including section 8 covering sellers' liability for harm caused by defective prescription drugs and devices.[2] We are still working on additional Restatement sections covering other topics.[3] Thus, final ALI approval of sec-

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** Reporter, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (Tentative Draft No. 2, 1995) and Frank B. Ingersoll Professor of Law, Cornell Law School. LL.B., 1962; LL.M., 1964, Harvard University.

The views expressed in this article are those of the author writing in his individual capacity. I do not purport to speak for the ALI nor for anyone else connected with the ongoing Restatement (Third) of Torts project on products liability. My co-reporter on that project, Aaron Twerski, has read this manuscript and generally agrees with its contents. But errors, if any, are mine.

1. *See* RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY (Tentative Draft No. 2, 1995) [hereinafter RESTATEMENT (THIRD), 1995 Tentative Draft]. At the time of this writing (November, 1995), we anticipate taking Council Draft No. 3 to the Council in December, 1995.

2. Section 8 applies explicitly to prescription devices as well as drugs. Courts generally recognize this application. *See, e.g.*, Brooks v. Medtronic, Inc., 750 F.2d 1227, 1230-32 (4th Cir. 1984) (holding the Restatement (Second) of Torts § 402A "prescription drug exception" applicable to cases involving cardiac pacemakers).

3. Council Draft No. 3 contains Chapters 2 and 3. Chapter 2 covers

tion 8, assuming it comes eventually, may be several years away.[4] But given the attention that section 8(c), which deals with liability for prescription drug designs,[5] has already received in the law reviews,[6] this explanation of and justification for section 8(c) is not premature.

II. TRADITIONAL JUDICIAL TREATMENTS OF PRESCRIPTION DRUG DESIGN LIABILITY

My purpose here is not to describe traditional treatments of prescription drug liability extensively or exhaustively. That task has been accomplished many times elsewhere,[7] including

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questions involving successor liability and apparent manufacturer liability. Chapter 3 involves tort liability not based on product defects at the time of sale. No further revisions are currently contemplated.

4. We will presumably present another Draft at the Annual Meeting in May, 1996. What happens thereafter involves contingencies about which I care not to speculate.

5. For the full text of § 8(c), see *infra* text accompanying note 30.

6. *See* Richard L. Cupp, Jr., *Rethinking Conscious Design Liability for Prescription Drugs: The Restatement (Third) Standard Versus a Negligence Approach*, 63 GEO. WASH. L. REV. 76 (1994) (discussing the proposed Restatement's clarification of the "unavoidably unsafe" doctrine and criticizing the proposed standard granting manufacturers of prescription products almost complete immunity from conscious design liability); Harvey L. Kaplan et al., *Third Restatement: New Prescription for Makers of Drugs and Medical Devices*, 61 DEF. COUNS. J. 64 (1994) (addressing the liability of manufacturers of prescription drugs and medical devices under § 103 of Council Draft No. 1); Elizabeth C. Price, *Toward a Unified Theory of Products Liability: Reviving the Causative Concept of Legal Fault*, 61 TENN. L. REV. 1277, 1329-37 (1994) (discussing the proposed Restatement's justifications for immunizing prescription drug manufacturers from design litigation); Teresa M. Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 TENN. L. REV. 1357 (1994) (criticizing the Tentative Draft's proposed standard for prescription products); Andrew Barrett, Note, *The Past and Future of Comment k: Section (4)(b)(4) of the Tentative Draft Restatement (Third) of Torts—Is It the Beginning Of a New Era for Prescription Drugs?*, 45 SYRACUSE L. REV. 1291 (1995) (proposing that Restatement (Second) of Torts § 402A cmt. k be abolished and replaced by Restatement (Third) of Torts § 4(b)(4) (Tentative Draft No. 1, 1994) in order to reconcile policy considerations of strict liability and the availability of prescription drugs).

7. For extensive citation of secondary treatments, see RESTATEMENT (THIRD), 1995 Tentative Draft § 8(c) cmt. d.

recently.[8] Instead, I will briefly sketch the development of the law to date (November, 1995) in order to provide the general background for a more focused examination of section 8(c). Preceding the ALI's 1964 approval of section 402A of the Restatement (Second) of Torts,[9] and until the mid-1980s, the view in this country was that prescription drug manufacturers were liable only for manufacturing defects[10] and failures to warn.[11] The universally recognized position, which is reflected in comment k to section 402A via the concept of "unavoidably unsafe products,"[12] was that courts properly refused to review the reasonableness of drug designs[13] where prescription drug companies adequately warned the FDA and medical care providers of knowable[14] risks attending consumption of their products.

Although reflected somewhat confusedly in comment k,[15] the main rationale for this position was that as long as the FDA screened new drugs scrupulously, and drug manufacturers adequately informed medical providers regarding the risks discoverable through diligent testing, the right drug designs would reach the right patients. Drugs might nevertheless (and unavoidably) cause harm, but they were not legally defective

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8. *See* sources cited *supra* note 6.

9. *See* RESTATEMENT (SECOND) OF TORTS § 402A (1965).

10. For citation of authorities, see RESTATEMENT (THIRD), 1995 Tentative Draft § 8 cmt. c.

11. For extensive citation of authorities, see *id.* cmt. d.

12. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965) provides:

> *k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use.

13. For discussions of the traditional approach, see James A. Henderson, Jr. & Aaron D. Twerksi, *A Proposed Revision of Section 402A of the Restatement (Second) of Torts*, 77 CORNELL L. REV. 1512, 1543 n.64 (1992); sources cited *infra* note 28.

14. The accepted view is that prescription drug manufacturers are liable only for known and knowable risks. *See, e.g.*, Toner v. Lederle Lab., 732 P.2d 297, 307 (Idaho 1987), *cert. denied*, 485 U.S. 942 (1988) (stating that "when the balance appears at the time of distribution to tip toward the benefit of a product, strict liability will not attach when an unexpected and unknown risk injures a user").

15. For criticisms of comment k to § 402A, see Cupp, *supra* note 6, at 81-82 nn.25-28.

for that reason alone. For courts to second-guess and thereby interfere with what was presumed to be a nearly perfect market arrangement in which physicians, as learned intermediaries, generally made correct decisions regarding whether a given drug was suitable for a given patient would discourage the development of worthwhile drugs.[16]

III. THE RECENT MOVEMENT TOWARD INCREASED JUDICIAL SCRUTINY OF PRESCRIPTION DRUG DESIGNS

Beginning in the 1980s, some courts re-examined traditional judicial reluctance to review the reasonableness of prescription drug designs.[17] Questioning the tacit implication of comment k that properly tested, approved, and marketed prescription drugs were invariably "unavoidably unsafe,"[18] courts in some jurisdictions began to require that either the judge as an initial matter, or the trier of fact under appropriate instructions, determine whether a given drug that caused harm was, indeed, unavoidably unsafe, notwithstanding drug companies' provision of adequate warnings.[19] In other words, in appropriate instances either the judge or the trier of fact are required to determine whether the design of a drug could not have been made safer without an unacceptable reduction in efficacy.[20]

In effect, what traditionally had been an irrebuttable pre-

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16. *See* Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 WASH. & LEE L. REV. 1139, 1141 (1985) (suggesting that imposition of strict liability on manufacturers of ethical drugs would stifle the research and development of new drugs).

17. *See generally* Henderson & Twerski, *supra* note 13, at 1543 n.65 (citing authorities questioning the application of comment k).

18. *See supra* note 12.

19. To test the hypothesis that a court is actually willing to impose liability solely on the basis of defective design, one must posit no concomitant breach of the duty to warn. *See generally* Henderson & Twerski, *supra* note 13, at 1539 & n.46 (noting that cases alleging defective design but no breach of the duty to warn are relatively rare).

20. When this task is given to the trier of fact, the test for liability is essentially the same as that applied to nonprescription products in § 2(b) of the proposed Restatement. *See* RESTATEMENT (THIRD), 1995 Tentative Draft § 2(b). For an explanation and illustration of how this test is applied, see *infra* notes 34-44 and accompanying text.

sumption that an approved, properly marketed drug was not defective in design became, over time, a presumption which the plaintiff could rebut with adequate proof. Consistent with this rebuttable presumption rationale, some courts now place the burden of proof on the plaintiff to show that the design of the prescription drug or device in question presents risks that outweigh its therapeutic benefits.[21] Other courts treat the "unavoidably unsafe" issue as a defense and place the burden on the defendant to prove that benefits outweigh risks.[22]

The main rationale for these more recent, nontraditional approaches to prescription drug design is that, upon reflection, drugs are not so different from other products as to deserve their traditionally favored position.[23] Of the courts willing to review drug designs, many do so with deference, at times bordering on the high degree reflected in section 8(c).[24] But the trend toward judicial design review of some kind is unmistakable. Much of the force behind this movement toward independent judicial scrutiny appears to stem from a conviction that only through a willingness to hold dangerous drugs defective will the promise in section 402A of strict tort liability be fulfilled.[25] Indeed, at least one court has gone so far as to hold a

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21. *See, e.g.*, Savina v. Sterling Drug, Inc., 795 P.2d 915, 927 (Kan. 1990) ("Plaintiff has presented no evidence to show that [defendant's drug] had a design defect that, if corrected, could have posed less of a risk.").

22. *See, e.g.*, Coursen v. A. H. Robins Co., 764 F.2d 1329, 1338 (9th Cir. 1985) (stating that comment k is an affirmative defense, with defendants carrying the burden of proof); Tansy v. Dacomed Corp., 890 P.2d 881, 886 (Okla. 1994) (holding comment k to be an affirmative defense only where the product has been properly manufactured, provides sufficient warning, its benefits justify its risks, and it is incapable of being made safe at the time of manufacture and distribution).

23. *See generally* Cupp, *supra* note 6, at 101 ("Prescription drugs are not unique in entailing design defects that might be a benefit to one class of users and a detriment to others."). *Cf. infra* text accompanying note 46.

24. *See, e.g.*, Williams v. Ciba-Geigy Corp., 686 F. Supp. 573, 577 (W.D. La.), *aff'd*, 864 F.2d 789 (5th Cir. 1988) (stating that Louisiana law heeds the principles articulated in comment k). For further discussion of *Williams*, see *infra* text accompanying notes 88-92.

25. *See, e.g.*, Hill v. Searle Labs., 884 F.2d 1064, 1069 (8th Cir. 1989) ("[O]nly exceptional products . . . in the field of prescription drug prod-

drug legally defective when it is shown to have caused a severely negative side effect, even when its overall benefits clearly outweigh its risks.[26] So strongly do some observers believe that courts are capable of holding prescription drug makers strictly accountable for the harms their products cause that one commentator has recently characterized his own decidedly nontraditional proposal—that courts routinely review drug manufacturers' design choices under a general negligence standard—as a balanced, "middle ground" approach.[27]

Before I proceed to explain and defend the position taken in section 8(c) of the Restatement (Third) of Torts: Products Liability, I should note that some influential courts have recently reaffirmed the traditional view that prescription drug designs are beyond the scope of judicial review when those drugs are reviewed by the FDA and properly marketed with full warnings.[28] I must confess that when Aaron Twerski and I first turned serious attention to this subject in the context of possibly revising section 402A of the Restatement (Second) of Torts, we thought in terms of retaining the traditional position rejecting independent judicial review of drug designs.[29] The follow-

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ucts[] should be excluded from the strict liability provisions [of § 402A].").

26. Allison v. Merck & Co., 878 P.2d 948, 954 (Nev. 1994) ("[A] drug manufacturer should, under the strict liability jurisprudence of this state, be held liable in tort even when the drug is 'properly prepared and marketed' (that is to say, non-negligently) and even when the known danger inherent in the drug may be what the comment calls 'reasonable.'").

27. *See* Cupp, *supra* note 6, at 105 ("[My approach] would establish a middle ground between the strict liability available in other design cases and the new Restatement's near immunity for prescription product designs.").

28. *See, e.g.*, Brown v. Superior Court, 751 P.2d 470, 477-78 (Cal. 1988) (holding that a manufacturer cannot be held liable if it has provided appropriate warnings and a doctor fails to communicate those warnings to the patient, or if the patient relies on the inaccurate information of others); Grundberg v. Upjohn Co., 813 P.2d 89, 90 (Utah 1991) (holding that sellers of properly marketed, FDA-approved drugs cannot be held strictly liable as a matter of law unless the manufacturer secured approval by furnishing misleading or otherwise flawed information to the FDA).

29. *See* Henderson & Twerski, *supra* note 13, at 1536 (stating the traditional approach as one limiting plaintiffs to actions for failure to

ing considerations led us to change our minds.

IV. PRESCRIPTION DRUG DESIGN LIABILITY UNDER SECTION 8(C) OF THE PROPOSED RESTATEMENT

A. The Proposal Itself

At its annual meeting in May, 1995, the ALI tentatively approved the following treatment of prescription drug design liability:

> A prescription drug or medical device is not reasonably safe due to defective design when the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits so that no reasonable health care provider, knowing of such foreseeable risks and therapeutic benefits, would prescribe the drug or medical device for any class of patients.[30]

Another part of section 8 contains this definition: "A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health care provider's prescription."[31] Comment f to section 8 suggests that the phrase "class of patients" in section 8(c) refers to more than a single patient,[32] although the number necessary to constitute a class is not specified.[33]

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warn versus a growing trend among a minority of jurisdictions permitting limited judicial review of drug designs).

30. RESTATEMENT (THIRD), 1995 Tentative Draft § 8(c).

31. *Id.* § 8(a).

32. *Id.* § 8 cmt. f, at 226. On its face, the phrase "class of patients" speaks in the plural. Comment f further speaks of "the appropriate drugs [reaching] the appropriate patients." *Id.* Critics have seized on the possibility that a drug's suitability to a single patient would prevent judicial review of the drug's design. *See, e.g.*, Cupp, *supra* note 6, at 97 ("Thus, if the prescription product could reasonably be prescribed to a single person—even if it were fatal as to all other persons to whom it is prescribed—the product would be immune from design liability [under the new Restatement.]"). This example is clearly beyond the intent of § 8(c). A reasonable doctor, knowing the facts, would never prescribe such a drug for any patient. The physical circumstances of the patients necessary to justify such a drug's prescription would have to be shared by many patients, and thus be fully verifiable, before a reasonable doctor would dream of prescribing it for anyone.

33. To specify exactly how many is unnecessary and would be patently

B. Some General Background: Design Liability for Nonprescription Products Under the Proposed Restatement

Section 2(b) of the proposed Restatement states the general rule defining defectiveness in design for nonprescription products.[34] To prove that a product design is defective, a plaintiff must show that a reasonable alternative design was possible and that omission of the alternative renders the product not reasonably safe.[35] Unless the defectiveness of defendant's design is self-evident,[36] courts engage in risk-utility balancing in comparing the actual product design sold by the defendant with the safer alternative advanced by the plaintiff.[37] Implicit in this approach is the idea that if the defendant's design presents unreasonable risks of harm in the hands of a foreseeable subset of users and consumers then the availability of a feasible, safer alternative may render defendant's design defective. This will be true even if defendant's design is reasonably safe in the hands of another subset of users and consumers. Stated differently, designed-in product safety is judicially imposed[38] on some users and consumers who do not want or need the added safety if the risks presented by the product in the hands of other users and consumers are substantial enough to warrant the imposition of the enhanced design on all users and consumers.[39]

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arbitrary. We trust judges to bring common sense to bear, even if academic critics do not always do so. *See supra* note 32.

34. Section 2(b) provides:

> [A] product is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.

RESTATEMENT (THIRD), 1995 Tentative Draft §2(b).

35. *See id.*

36. *See id.* § 3.

37. The relevant factors are described in RESTATEMENT (THIRD), 1995 Tentative Draft § 2 cmt. e.

38. In most cases, when a court finds a product design defective, the court is saying that the design feature whose absence (or presence) constitutes a defect should be included (or excluded) in all product units in the same product line.

39. Other writers understand this point. *See, e.g.*, Cupp, *supra* note 6,

A concrete example will help make this fundamental point clear. Imagine two families, the Hendersons and the Twerskis, who are next door neighbors. Each has a three year old child with a persistent cough. Both families buy identical hot-water vaporizers to use at night for their child's benefit.[40] The vaporizers are designed to allow the lid to be lifted off with one hand, facilitating refilling. But the lack of a secure screw-on top permits hot water to gush out through the wide neck of the underlying two-gallon jar if the vaporizer is tipped over while operating. The Twerskis are careful parents. They read the instruction booklet carefully, placing the vaporizer where their child cannot reach it.[41] The Twerskis have never had a problem and are happy with their vaporizer, which has helped their child's condition.

In contrast, the Hendersons in our hypothetical are not so careful. They barely glance through the instruction book, and place the vaporizer within easy access of their child, on a stool near his bed. One night, the Hendersons' child gets up to go to the bathroom, knocks the vaporizer off the stool, and is injured by scalding water.

The Hendersons bring an action against the vaporizer manufacturer, claiming that an alternative design employing a screw-on top, at little extra cost, would have prevented their child's injuries.[42] At trial, testimony reveals that a significant number of other children have been injured in basically the

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at 99 (employing an automobile as an example). The writer's error in arguing in favor of broad judicial review of prescription drug designs is in failing to understand the important differences between markets for automobiles and markets for prescription drugs. Automobiles are distributed indiscriminately to all members of the public who are presumably competent to operate them. Judicial oversight of vehicle design is justified because some drivers are unable, on their own, to manage risks adequately. Prescription drugs are distributed only through learned intermediaries, after screening by the FDA. Judicial oversight of drug design is significantly more questionable.

40. This hypothetical is based loosely on McCormack v. Hankscraft Co., 154 N.W.2d 488 (Minn. 1967).

41. In the actual case on which this hypothetical is based, the instructions were misleading. *Id.* at 495.

42. With such a top, scalding water would not gush out in large quantities.

same way and that the pecuniary costs of adopting the screw-on top would be a few dollars per unit.[43] Under the design defect rule in the proposed Restatement, the trier of fact would be allowed to find the vaporizer sold to the Hendersons, Twerskis and other customers to be defective.[44]

Exposed to potential liability for every product unit design with a lift-off top, the vaporizer manufacturer almost certainly would switch to screw-on tops, passing on the added costs to future buyers.[45] The Twerskis, who were always careful to avoid the risk of spill-over, end up paying more in the future for hot-water vaporizers than their needs require,[46] with some of the extra funds going toward redesign to help protect people like the less-careful Hendersons. This wealth-transfer implication of judicial review of product design is not necessarily wrong.[47] But it is very real.

As the foregoing observations reveal, judicial review of the reasonableness of nonprescription product designs is inherently, and potentially unacceptably, paternalistic. For that reason courts are advised to defer, whenever reasonable, to consumer preferences expressed in the market, especially when the risks are obvious, generally understood, fully warned against, and avoidable through careful product use or consumption.[48] Furthermore, when negative third party effects are minimal,[49] courts should hesitate before imposing the added costs of greater safety on users or consumers who do not volunteer to pay for additional safeguards when choosing which product

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43. Nonpecuniary costs of making the design change would include a reduction in the ease of refilling.

44. The screw-on top could be found to constitute a "reasonable alternative design" under § 2(b). *See supra* note 34 and accompanying text.

45. *Cf. supra* note 38 and accompanying text.

46. The Twerskis will pay more in at least two ways: (1) they will pay more money for the new vaporizer; and (2) they will invest more time and energy refilling it.

47. Certainly it is appropriate to the extent that the injured victims are third-person bystanders. Product users should pay, up to reasonable limits, to prevent inadvertent injury to third persons. Whether the child in the vaporizer example is a third-person bystander is unclear.

48. This combination will turn a greater percentage of product users and consumers into Twerskis rather than Hendersons.

49. *See supra* note 47.

designs to buy in the marketplace.[50] Of course, when the foregoing conditions are not present, as in the hot-water vaporizer hypothetical,[51] judicial supervision in the context of nonprescription product design is not only justified, but necessary, in order to compensate for market failure. As the proposed Restatement recognizes, when the plaintiff can show that a safer alternative design was available at an acceptable cost,[52] and would have reduced or avoided plaintiff's harm, a prima facie case of defective design is made out.

C. The Rationale Supporting a Limited Role for Judicial Review of Prescription Drug Designs Under the Proposed Restatement

Before considering the legal precedent supporting the position taken in section 8(c) of the proposed Restatement,[53] it will be useful to consider the rationale underlying that position. Although I can hardly disclaim at least a trace of bias, the "no reasonable provider would prescribe the drug" rule flows logically, I am tempted to say ineluctably, from what has preceded ALI approval of section 8(c). If the good sense at the heart of the pre-1980s position denying judicial review of drug design[54] remains, substantial deference to a marketplace for prescription drugs that appears to function almost perfectly is warranted.[55] Assuming that recent decisional trends favoring

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50. Excessive paternalism is both unfair and wastefully inefficient.

51. The primary victims were helpless, innocent children; the injuries were severe, recurrent, and the risks were not obvious; and the change in the design was relatively minor and inexpensive.

52. Among the factors to be considered are "the effects of the alternative design on production costs, product longevity, maintenance and repair, esthetics, and marketability." RESTATEMENT (THIRD), 1995 Tentative Draft § 2 cmt. e.

53. *See infra* text accompanying notes 80-111.

54. That position held that a combination of FDA regulation, the expertise of informed "learned intermediaries," full warnings from manufacturers, and virtual nonexistence of third-party effects warrants a denial of judicial review of prescription drug designs.

55. The argument is not that the market for prescription drugs and devices is infallible. Mistakes do occur. But given the regulatory oversight by the FDA and the role of the medical profession, the market works remarkably well.

judicial review render a continuation of the pre-1980s position unacceptable in a new Restatement,[56] one could argue that the only tenable position that the Institute could take is the one it has, albeit tentatively to this point, taken. When one combines the force of this logic with the fact that section 8(c) is supported by recent caselaw,[57] one may well wonder how a reasonable person could disagree with the Institute's position in this regard.[58]

Of course, I am aware that a number of reasonable persons have so disagreed. This disagreement has come from both directions: some critics think that section 8(c) has gone too far, and opened the door to what is tantamount to strict liability for drug designs that harm patients;[59] while others believe we have invoked what amounts to the traditional rule of immunity from design liability.[60] Although fellow reporter Aaron Twerski and I have learned to accept criticism stoically and, for the most part, quietly, this Article is an appropriate forum for a respectful response to these critics. As I understand them, some critics from the drug industry believe that plaintiffs will always be able to get a medical "expert" to testify that a new drug is better than the old, and therefore, a defendant's drug would not be prescribed by knowledgeable physicians to any class of patients. Coupled with the reality that many physicians will continue (reasonably) to prescribe defendant's drug, pharmaceutical companies will be exposed (unfairly) to what amounts to strict liability.

Observe that this argument rests on one or the other of two questionable factual premises: first, that believable false testi-

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56. The clear and growing trend in reported decisions favors some sort of judicial review. *See supra* notes 17-27 and accompanying text. To deny this trend altogether in a new Restatement of the Law would require very powerful reasons, which we are unable to muster.

57. *See infra* notes 80-102 and accompanying text.

58. Those who know me personally will, I trust, detect a bit of tongue-in-cheek here.

59. This sentiment was advanced by some drug industry representatives who attended the Pfizer Lecture, which I delivered at Rutgers School of Law—Newark in November, 1995 and which inspired this article.

60. *See, e.g.*, Cupp, *supra* note 6, at 96-98; Schwartz, *supra* note 6, at 1378-81.

mony will always be available to plaintiffs to the effect that the defendant's drug should not be prescribed for any class of patients; or second, that even if such testimony is accurate, many physicians will, unreasonably, continue to prescribe defendant's drug even though they should not. The former premise, unverifiable empirically, is too cynical to accept on rhetoric alone. The latter suggests a massive market breakdown that, if true, should be the joint responsibility of the prescribing physicians, for misprescribing obsolete drugs, and of the drug industry for continuing to promote the prescription and consumption of such drugs. In either event, section 8(c) would appear to be the correct liability rule for allegedly defective drug designs.[61]

Academic critics advocating a more pro-plaintiff position than that set forth in section 8(c) prefer an approach to prescription drug design that is close to, if not identical with, that taken in connection with nonprescription products in section 2(b) of the proposed Restatement. On this view, triers of fact, whether judges or juries, should engage in risk-utility analysis to decide whether a harm-causing drug design presents unreasonable risks of harm.[62] Thus, even if a drug were to provide net benefits to one or more identifiable classes of patients, if it were also shown to be detrimental to other classes of patients for whom one can only assume the drug was "misprescribed" by medical care providers,[63] its design could be found defective if the jury concluded that the drug caused, in the overall aggregate, more social harm than good.[64] In effect, courts would review patterns of drug prescription and consumption looking for market failures, as in the vaporizer hypothetical discussed above.[65]

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61. Even if both premises are true to some extent, the drug industry is better off with § 8(c) than with the wide-open negligence approach advocated by some critics and courts.

62. *See, e.g.*, Cupp, *supra* note 6, at 91.

63. I say "misprescribed" because if the system worked as it should, drugs would not be prescribed for patients for whom the risks exceed the expected benefits. When that occurs one can only conclude that the market has failed. *Cf.* discussion *infra* text accompanying notes 110-12.

64. If I am correct in concluding that the harm would be caused by "misprescription," one might fault the prescribers rather than the drugs.

65. *See supra* text accompanying notes 40-46.

One critic's analysis of how such an approach would apply in a hypothetical case involving prescription breast implants reveals its misconceptions.[66] The author assumes the availability of two breast implant designs, one of which involves a greater (but nevertheless relatively remote) risk of disease-related side effects while offering a softer, more natural appearance.[67] The other implant design is likely to harden and thus appear and feel less natural, but presents a lower risk of side-effect disease.[68] In some patients, the author further hypothesizes, the hardening associated with the second design can present health risks serious enough for doctors to reasonably recommend the softer implant.[69] Many patients for whom the second design presents no health risks prefer the softer implant for aesthetic reasons,[70] the author continues, and their doctors acquiesce in their presumably informed but unfortunate choices in this regard.[71] The author concludes that if the aggregate health risks of "improper" (i.e., aesthetic) use of the softer implant outweigh the benefits to patients for whom breast hardening is risky, then a jury could (and should) determine that the softer implant design is defective.[72]

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66. *See* Cupp, *supra* note 6, at 101-02.

67. *Id.* The author admits that breast implant-related risks may in fact be nonexistent. *Id.* at 102 n.156.

68. *Id.* at 101.

69. *Id.* at 102.

70. *Id.*

71. I fail to see how such a choice could be said to be improper, especially since the author concedes that risks of disease in the softer implant are probably nonexistent. *See id.* at 102 & n.156.

72. Specifically, the author concluded that:

> Implants cause more severe hardening in some users' breasts than in others. Thus, for users who experience severe hardening it might be reasonable to prescribe a change to polyurethane-coated implants in spite of the perhaps remote cancer risk they pose. And if a design alteration incorporating the coating were available without the risk of design liability, doubtless many sellers would be tempted to allow its use by consumers suffering less-than-severe hardening to fulfill their desire for a more natural feel. If plaintiffs' claims that the product is carcinogenic are correct, this benefit would come at the cost of causing cancer in some women. Because a class of women exists for whom prescribing the polyurethane coating is reasonable, however, under

The author's reaction to the foregoing hypothetical is flawed in several respects. Finding the softer implant design defective prevents its use by those women for whom it is the healthiest choice.[73] Moreover, a finding of defectiveness also deprives those knowingly willing to run the health risks of the softer alternative for aesthetic benefits. It is paternalistic in the extreme to conclude that a woman's informed choice to incur remote health risks for aesthetic reasons does not deserve to be respected.[74] Bear in mind that we are assuming throughout the analysis that full, adequate warnings have been given to everyone concerned.[75] With proper warnings, the choice of

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> the new Restatement the design is the "drug of choice" for them and must not be burdened with judicial scrutiny even if the design decision was on the whole unreasonable.

Id. at 102. *See also* Richard L. Cupp, Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Products Transactions*, 21 FLA. ST. U. L. REV. 873, 902-03 (1994) (discussing how risk/utility balancing would lead to different results depending on whether a court applies a strict liability or a negligence version of the test).

73. The softer implant will leave the market, often against the wishes of consumers. *See supra* note 38 and accompanying text. Indeed, the *company* making the softer implant will likely leave the market. *See, e.g.*, *In re* Dow Corning Corp., No. 95-20512, 1995 WL 495978, at *1 (Bankr. E.D. Mich. Aug. 9, 1995) (noting that the debtor, a manufacturer of silicone gel breast implants and related products for nearly 30 years, ceased producing those items and sought bankruptcy protection as a result of voluminous personal injury litigation stemming from their use).

74. Disregarding an individual's informed decision runs counter to deeply-held values of personal choice and sovereignty in our culture. Cosmetic surgery, even when performed purely for aesthetic reasons, is not condemned as tortious merely because it involves unavoidable risks of injury. The same should hold true for cosmetic prescription medical products. *See, e.g.*, Artiglio v. Superior Court, 27 Cal. Rptr. 2d 589 (Ct. App. 1994) (barring strict liability design defect claims in cases involving "merely cosmetic" breast implant devices). For an argument that courts should allow strict liability for primarily cosmetic as opposed to therapeutic medical products, and models for identifying products as primarily cosmetic, see Cupp, *supra* note 72, at 906-09.

75. In the real-life litigation involving breast implants the plaintiffs' major allegations are based on failure-to-warn. *See, e.g.*, Toole v. McClintock, 999 F.2d 1430 (11th Cir. 1993); *In re* Silicone Gel Breast Implant Prod. Liab. Litig., 887 F. Supp. 1463 (N.D. Ala. 1995); Desmarais v. Dow Corning Co., 712 F. Supp. 13 (D. Conn. 1989). This

whether to have implant surgery and, if so, which design is preferable for which patient, should be left to the market; that is, to women, informed by their doctors. If one responds by suggesting that some doctors may *misinform* patients and *misprescribe* implants by urging their patients to take unnecessary risks, then the proper remedy is to place the responsibility on the doctors who engage in such substandard behavior.[76]

The proposed Restatement would almost certainly respond to the foregoing hypothetical by rejecting the defectiveness of the softer implant design as a matter of law.[77] To deny access to fully informed women who choose to use the softer implant, whether for health reasons or aesthetic preferences, is presumptively inappropriate. Unless one is ready to admit to the possibility of frequent, massive failures in the "FDA-learned intermediary" market system, the rule tentatively adopted by the ALI represents the appropriate judicial response to prescription drug design liability.

D. Caselaw Supporting the Institute's Position Is Stronger Than Has Been Made to Appear

Critics of the proposed Restatement's treatment of prescription drug design have pointed out that section 8(c) is bound to be controversial because it represents the most extreme departure from existing decisional law to be found in the entire Restatement project.[78] This is an inaccurate characterization, as shall now be made clear. But first, a confession. In the

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article is not concerned with that traditional, but alternative, basis of liability.

76. *See supra* note 64.

77. In the hypothetical there are at least two classes of patients for whom the softer implant is the one of choice for whom reasonable, informed health care providers would prescribe the product.

78. *See, e.g.*, Cupp, *supra* note 6, at 98.

> [I]t seems unlikely that courts will uniformly adopt the new Restatement's version of the doctrine. Unlike many of the ALI's revisions to section 402A, its language addressing prescription products is far from a restatement of present law. Indeed, as discussed more fully below, the new Restatement claims only one jurisdiction as presently utilizing its approach to conscious design defect actions, and even that claim is questionable.

Id.

Reporters' Notes to section 8(c)[79] Aaron and I did not do complete justice to the emerging body of law that supports our position. Essentially, the Notes relied for direct support on a single decision, *Tobin v. Astra Pharmaceutical Products, Inc.*[80] In that case, the Court of Appeals for the Sixth Circuit affirmed a verdict and judgment in favor of a young woman who had taken a prescription drug during pregnancy, allegedly resulting in cardiac failure and a heart transplant.[81] The drug in question was designed to prolong pregnancy and prevent premature delivery, but also posed serious risks of potentially fatal reactions in patients with plaintiff's presenting conditions.[82] At the close of trial, the jury found that the drug provided no benefits to any class of patients and created such serious risks that it was defective in design.[83] The Court of Appeals concluded, "We find that there was sufficient evidence before the jury to conclude that a prudent manufacturer knowing all the risks would not market [the drug]."[84]

The ALI has tentatively adopted a slightly different test: Would a reasonable provider knowing all the risks have prescribed the drug? The reason for preferring the provider's perspective relates back to the discussion earlier of the appropriateness, in the context of nonprescription product design review, of "netting out" all risks and benefits globally, and being willing in an appropriate case to benefit some users or consumers at the cost of others.[85] As reflected in the current draft, that willingness is appropriate in connection with nonprescription product designs generally. But it is inappropriate in connection with prescription drugs. Assuming that a care provider might reasonably prescribe a drug for one class of patients to whom it delivers net benefits, but not to most others, to whom it delivers net detriments, the provider perspective seems preferable. By comparison, the manufacturer's perspective may

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79. *See* RESTATEMENT (THIRD), 1995 Tentative Draft § 8 cmt. f.

80. 993 F.2d 528 (6th Cir.), *cert. denied sub nom.*, 114 S. Ct. 304 (1993).

81. *Id.* at 532.

82. *Id.* at 533.

83. *Id.* at 532.

84. *Id.* at 540.

85. *See supra* text accompanying notes 62-77.

invite a more global, and inappropriate, netting out of costs and benefits over different classes of patients. Stated differently, if a drug exists that is clearly the drug of choice for one or more classes of patients, it should not be denied them simply because other patients who should not take the drug do, in fact, take it and suffer harm.

Notwithstanding the *Tobin* court's reliance on a reasonable manufacturer's perspective, it is clear from the opinion that the court was unready to sacrifice—by labeling a drug defective—any class of patients for whom it might be the drug of choice. The opinion leaves no doubt that defendant's proof of the drug's efficacy for *any* class of patients was weak and inconclusive.[86] In future cases, the proposed Restatement's reliance on the provider's perspective should help to assure that liability for drug design will not be imposed in ways that may help some patients while sacrificing others.[87]

Contrary to the impression created in the Reporters Notes in Tentative Draft No. 2, *Tobin* is not the only reported decision to support the position adopted in section 8(c). For example, in *Williams v. Ciba-Geigy Corp.*,[88] a federal district court in Louisiana was willing to consider the possibility that the traditional bar to prescription product design review might be relaxed.[89] Nonetheless, the court imposed a heavy burden on the plaintiff to provide evidence of "an articulable basis for disregarding the FDA's determination that the drug should be available."[90] In granting summary judgment in favor of the pharmaceutical company, the court emphasized the drug's efficacy for certain classes of patients, notwithstanding its sometimes severely negative side effects.[91]

No evidence in the record tends to impugn the utility of

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86. *Tobin*, 993 F.2d at 538-40.

87. *See supra* text following note 77.

88. 686 F. Supp. 573 (W.D. La.), *aff'd*, 864 F.2d 789 (5th Cir. 1988).

89. *Id.* at 577.

90. *Id.*

91. The drug in question, Tegretol, is effective in the treatment of epileptic symptoms and trigeminal neuralgia. *Id.* at 578. The plaintiff suffered from Stephens-Johnson syndrome, "a serious skin condition known to be an adverse reaction to the defendant's product. . . . " *Id.* at 574.

> Tegretol. There is no showing that any [other] drug . . . is effective in treating [plaintiff's disorder]. Tegretol is indicated only for those sufferers of psychomotor and grand mall seizures who do not respond to, or are endangered by, more conventional anticonvulsants which have serious side effects of their own. . . . The consequences of the nonavailability of Tegretol for those patients who suffer serious seizures, which can be fatal if not controlled, but who cannot take other anticonvulsants, would be grave indeed.[92]

The decision in *Williams* supports the approach to prescription drug design liability taken in the proposed Restatement.

Another decision supporting the proposed Restatement's position regarding drug design liability is *Ortho Pharmaceutical Corp. v. Heath*.[93] There, the court adopted a test[94] that, facially, more closely resembles the "reasonableness under all the circumstances" approach recommended by several recent critics of section 8(c).[95] But in describing the manner in which the trial court should instruct the jury on remand, the Supreme Court of Colorado revealed unambiguously that the drug should be found nondefective if the jury concluded that the drug was the drug of choice for at least one class of patients.[96] The general question for the jury was whether the benefits of the defendant's drug, containing thirty milligrams of estrogen more than an alternative drug on the market, did or did not outweigh its risks.[97] In addressing the circumstanc-

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92. *Id.* at 578.

93. 722 P.2d 410 (Colo. 1986).

94. *Id.* at 413-14.

95. *See* Cupp, *supra* note 6, at 105; Schwartz, *supra* note 6, at 1370-71.

96. *Ortho Pharmaceutical Corp.*, 722 P.2d at 415 (holding that the defendant drug company was entitled to a jury instruction which would allow the jury to find for defendant if the drug's utility greatly outweighed its known risks, its benefits could not be obtained another way, and the risk was unavoidable given the state of medical science). The standard in the proposed Restatement similarly provides that a drug or medical device is defective if its "foreseeable risks . . . are sufficiently great in relation to its foreseeable therapeutic benefits . . . ." RESTATEMENT (THIRD), 1995 Tentative Draft § 8(c). This standard will present comparable issues to the trier of fact. *See id.* cmt. f.

97. *See Ortho Pharmaceutical Corp.*, 722 P.2d at 416 (holding that the question of whether the drug's benefits outweigh its risks is one for the

es under which one or the other conclusion would be warranted, the court concluded:

> Here, the record contained testimony which indicated that the increased risks of adverse reactions occasioned by the extra thirty milligrams of estrogen outweighed any benefits the product might produce. The record also contained evidence that [defendant's drug] was the only available product for patients who experienced breakthrough bleeding *and therefore, produced benefits that outweighed any increased risk.*[98]

The emphasized language clearly indicates that if one class of patients is found to exist for whom defendant's drug is the one of choice, then it is not defective.

Contrary to what critics have claimed, the principle underlying section 8(c) is deeply imbedded in recent caselaw addressing the issue of prescription drug design defects, even when the holdings adopt different rules of liability. A good example is the well-known decision in *Toner v. Lederle Laboratories.*[99] *Toner* does not provide direct support for the proposed Restatement's position. Indeed, *Toner* adopts a position that the proposed Restatement clearly rejects: i.e., that a plaintiff may succeed by proving that the defendant pharmaceutical company could and should have developed, received FDA approval of, and marketed an improved drug that would have rendered the drug actually produced one that no knowledgeable medical care provider would have prescribed for any class of patients.[100] If one examines the reasoning in the decision carefully, however, *Toner* implicitly rests on the premise embraced by the proposed Restatement.

To appreciate the point being made, one should ask: "What if plaintiff's proof regarding defendant's alleged negligence in failing to develop an alternative drug fails?" The court in *Toner* is careful to point out that at the time the plaintiff consumed defendant's drug it was the only one of its kind approved by

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jury).

98. *Id.* at 414 (emphasis added).

99. 732 P.2d 297 (Idaho 1987), *cert. denied*, 485 U.S. 942 (1988).

100. *See id.* at 306 (holding that the "unreasonable risk" doctrine applies only if there is no feasible, less risky alternative).

the FDA.[101] By allowing plaintiff to argue that the defendant should have developed another drug that would have provided the same benefits at lower risk, the court, in effect, allowed plaintiff to show that this circumstance was the result of defendant's negligence. The clear implication is that if plaintiff fails to prove defendant's negligence in not developing the alternative drug, then the drug at issue is not defective for precisely the reason embraced by the proposed Restatement—that, quite independently from any "global risk/benefit assessment," reasonable health care providers properly would have prescribed defendant's drug to a substantial class of patients since it was the only one of its kind available to them.[102]

Of course, the fact remains that even if decisions like *Toner* implicitly embrace the underlying premise of section 8(c), the "negligent failure to develop a better drug" aspect is one rejected by the proposed Restatement. Why does the new Restatement refuse to allow a plaintiff to attempt to prove defendant's negligence in failing to develop and market a safer alternative drug? In effect, the holding in *Toner* substitutes judicial decisionmaking by triers of fact for the FDA administrative process of drug approval. The FDA process is a long, drawn out, meticulous process; some critics argue too much so.[103]

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101. *Id.* at 300 ("[A]t the time of Kevin Toner's vaccination, the whole cell pertussis vaccine was the only pertussis vaccine licensed by the Food and Drug Administration (FDA) for use in the United States. It remains the only licensed vaccine today.").

102. The fact pattern in *Toner* may be unique. Apparently, an alternative drug had been developed in Japan. *Id.* (quoting Toner v. Lederle Labs., 779 F.2d 1429, 1431 (9th Cir. 1986), *certified question answered by*, 732 P.2d 297 (Idaho 1987), *cert. denied*, 485 U.S. 942 (1988)). Thus, the plaintiff did not need to hypothesize an alternative drug that did not exist. If the holding in *Toner* is limited to that unique fact pattern, it will have little application to future cases.

103. For a detailed discussion on the drawbacks of the FDA's requirements for drug approval, see generally Harvey Teff, *Drug Approval in England and the United States*, 33 AM. J. COMP. L. 567, 568 (1985) (noting criticisms of an "unnecessarily complex bureaucratic process" and an "unduly adversarial stance towards the pharmaceutical industry"); John P. Dillman, Note, *Prescription Drug Approval and Terminal Diseases: Desperate Times Require Desperate Measures*, 44 VAND. L. REV. 925, 939 (1991).

Drug companies seeking approval must do more than advance expert opinion that an alternative drug *could* be developed. They must produce a prototype and test it rigorously for years.[104] Only after rigorous and redundant testing supports the conclusion that a new drug is useful and acceptably risk-free will approval be given.[105] The proposed Restatement reflects the view that courts are institutionally unequipped to substitute their approval of a proposed new drug, on a case-by-case basis, for that of the FDA.[106] To be sure, the proposed Restatement allows courts to second-guess the FDA on the flip-side question of whether a drug approved by the FDA and marketed by a defendant should *not* have been approved and marketed. But the test by means of which such second-guessing occurs—whether no reasonable provider with full knowledge would prescribe the drug for any class of patients[107]—is deliberately drawn in such a way as to provide plaintiffs access to triers of fact only in relatively rare cases.[108] In contrast, the rule in *Toner* is couched in such a manner as to allow access to triers of fact almost routinely.[109]

Thus, as in *Toner*, when defendant's drug is the only one of its kind on the market and serves what members of the medical profession ostensibly believe to be a useful purpose, plaintiff should not reach the trier of fact. It is theoretically possible

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104. Applications for FDA Approval to Market A New Drug or Antibiotic, 21 C.F.R. § 314.126 (1995).

105. *Id.*

106. For a seminal treatment of the limits of adjudication, see generally Lon L. Fuller, *The Forms and Limitations of Adjudication*, 92 HARV. L. REV. 353, 394-404. For application of Fuller's insights to product design litigation see generally, James A. Henderson, Jr., *Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication*, 73 COLUM. L. REV. 1531, 1542-44 (1973).

107. *See supra* text accompanying note 30.

108. *See* RESTATEMENT (THIRD), 1995 Tentative Draft § 8(c) cmt. f ("Given this very demanding standard, liability is likely to be imposed only under unusual circumstances.").

109. The real constraint under a general rule may come in the form of judicial resistance to plaintiffs' heavy reliance on medical expert witnesses under Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) (establishing standards for the admissibility of scientific evidence in federal trials). But on its facts, *Toner*'s holding may be much narrower. *See supra* note 102.

under the proposed Restatement that a plaintiff might be able to show that, notwithstanding a drug's exclusivity for treating a particular medical condition, no reasonable, knowledgeable provider would prescribe the drug for any class of patients. But as a practical matter that is quite implausible.

Given the importance of the issue of "support in the caselaw" to my thesis, I will develop a few more steps at the risk of appearing to belabor the point. First, when commentators urge the position that harms to one class of patients are properly weighed against benefits to other classes, it must be remembered that such massive misprescription of drugs and medical devices almost certainly must be caused by defendants' providing inadequate warnings to medical care providers. And, as one might expect, most of the cases advocating negligence-based review of drug designs also impose liability on the alternative ground of failure to warn.[110] I would like "pro-plaintiff" critics of section 8(c) to try to compose a list of reported decisions in which defective design is the only basis for liability, not undercut by failure to warn. Examples abound in nonprescription product design cases.[111] Why do they not also abound in the context of prescription drugs?

More fundamentally, running through the relevant decisional law is a deep-seated cultural assumption, reflected in *Toner* and many other cases, that if a drug truly is the only one that can help a class of patients who otherwise are going to suffer serious medical injury, it would be unacceptable to deny them the drug just because doctors are misprescribing it to patients who should not be taking it. If liability is justifiable on the basis of failure to warn, so be it. Given exposure to such liability, however, better warnings will presumably be forthcoming and the drug will remain on the market. For courts to imply that the design of such a drug may be defective even if adequate warnings were provided is to embrace a questionable premise. Thus, the rule in section 8(c) is not only supported in

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110. *See, e.g.*, Hawkinson v. A.H. Robins Co., 595 F. Supp. 1290 (D. Colo. 1984).

111. *See, e.g.*, Pokorny v. Ford Motor Co., 902 F.2d 1116 (3d Cir.) (van), *cert. denied*, 498 U.S. 853 (1990); Myers v. Pennzoil Co., 889 F.2d 1457 (5th Cir. 1989) (valve on oil ring); Nettles v. Electrolux Motor, A.B., 784 F.2d 1574 (11th Cir. 1986) (chainsaw).

the caselaw but strikes a deep nerve in the judiciary's shared sense of interpersonal fairness.

V. CONCLUSION

The portions of the Restatement (Third) of Torts: Products Liability tentatively approved by the American Law Institute at its annual meeting in May, 1995, include a provision imposing liability on prescription drug manufacturers for harm caused by defective drug designs. The test for drug design liability in section 8(c) of the proposed Restatement is deliberately narrow: a drug is defective in design if no reasonable health care provider, knowing all the relevant facts, would prescribe the drug for any class of patients. Traditionally, American courts have refused to review the reasonableness of prescription drug designs, imposing liability only for harm caused by manufacturing defects and failures to warn the medial profession of relevant risks. Recent years have witnessed a decisional trend favoring judicial review of prescription drug designs. Currently, the courts appear to be testing a number of approaches, and confusion is the order of the day.[112]

The rule in the proposed Restatement represents one path taken explicitly by several courts and imbedded in the decisions of many more. Its policy reflects the view underlying the traditionally unanimous refusal of courts to review prescription drug designs: confidence in a prescription drug market system involving rigorous FDA regulation, learned and informed medical care providers, full and adequate warnings of risks, and the substantial absence of third-party effects. What was traditionally an irrebuttable presumption that prescription drug designs were acceptable has effectively become, under the rule recognized in the proposed Restatement, a presumption of nondefectiveness rebuttable by plaintiffs on very narrow

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112. *See* Cupp, *supra* note 6, at 79.

> Scholars appear nearly unanimous in their criticism of the original language of comment k as a model of confusion. Confirming this criticism, courts have adopted a broad range of conflicting interpretations of the doctrine. Consensus about the unavoidably unsafe doctrine seems limited to the belief that it exists and that it is important.

Id.

grounds. The Restatement rule also reflects the view that as long as one or more classes of patients need a particular drug, it should not effectively be removed from the market by judicial decree just because other patients are put at risk due to inappropriate prescription of the drug.

Some industry critics of the proposed Restatement's position on prescription drug design liability argue that section 8(c) will open the door to liability in most cases. That surely is not the intent reflected in the Comments to the section. Moreover, this criticism rests on premises with no empirical foundation.

Academic critics tend to favor an approach that would treat prescription drugs very much like nonprescription products. The proposed Restatement reflects the view that prescription drugs present quite different product design issues, unique unto themselves and clearly beyond the institutional competence of courts to manage. These critics have also exaggerated the extent to which the proposed Restatement represents a departure from judicial precedent. In part, this exaggeration stems from shortcomings in the existing (as of November, 1995) Reporters' Notes accompanying the prescription drug design section in Tentative Draft No. 2. As a Reporter to the Restatement (Third) of Torts: Products Liability, I hope this article sets the record straight in this regard. Needless to say, followers of the Restatement project can expect an expanded set of Reporters' Notes on this subject in the next draft of section 8(c) presented to the ALI membership.